

GP - 1041/LF

Priority or Docket No. 107-145D-C-C

PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re prior application of: Said El Shami

Application No.: 09/036,819 Group No.: 1641

Filed: March 9, 1998 Examiner: S. Devi, Ph.D.

For: METHOD FOR MEASURING FREE LIGANDS IN BIOLOGICAL FLUIDS,
AND ASSAY KITS FOR MEASURING SAME

TECH CENTER 1600/2900

NOTE: "In addition to identifying the application number of the prior application, applicant should furnish in the request for an application under this paragraph the following information relating to the prior application to the best of his or her ability: (i) Title of invention; (ii) Name of applicant(s); and (iii) Correspondence address." 37 C.F.R. § 1.53(d)(8).

Box CPA

Assistant Commissioner for Patents
Washington, D.C. 20231

#10
CPA
C. S. Quett
11/4/99

CONTINUED PROSECUTION APPLICATION (CPA)
(37 C.F.R. § 1.53(d))

NOTE: A continued prosecution application can only be used to file a divisional or continuation of a prior nonprovisional application and can NOT be used to file a continuation-in-part application. 37 C.F.R. § 1.53(d)(1).

WARNING: While facsimile transmission can be used to obtain a date of transmission for this correspondence the date on the certificate of transmission (§ 1.8(a)) of an application under § 1.53(d) (CPA) is not controlling (or even relevant), in that a CPA filed by facsimile transmission will not be accorded a filing date as of the date on the certificate of transmission (§ 1.8(a)) unless Office records indicate, or applicant otherwise establishes pursuant to § 1.6(f), receipt in the Office of the complete application under § 1.53(d) on the date on the certificate of transmission, and that date is not a Saturday, Sunday, or Federal holiday. 37 C.F.R. § 1.8(b)(3) and 62 FR 53131, 53133, October 10, 1997. Requests for a continued prosecution application filed by facsimile transmission should be clearly marked "Box CPA". 37 C.F.R. § 1.53(d)(9).

CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10

*(When using Express Mail, the Express Mail label number is mandatory;
Express Mail certification is optional.)*

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents and Trademarks, Washington, D.C. 20231

37 C.F.R. § 1.8(a)

37 C.F.R. § 1.10*

with sufficient postage as first class mail. as "Express Mail Post Office to Addressee".
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TRANSMISSION

transmitted by facsimile to the Patent and Trademark Office.


Signature

LAURA VELARDE

Date: 10/28/99

(type or print name of person certifying)

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(Continued Prosecution Application (CPA) [4-2]—page 1 of 10)

Before using the CPA procedure note that a CPA application § 1.53(d) cannot be amended to delete the specific reference to a prior application (e.g., for patent term purposes), as well as the specific reference to any application to which the prior application contains a specific reference under 35 USC 120, 121 and 365(c) and the expiration date under 35 USC 154(b)(2) of any patent issuing from the § 1.53(d) application will be based upon the filing date of the prior application (or the earliest application to which the prior application contains a reference under 35 USC 120, 121, and 365(c)). 62 FR 53131, 53145, October 10, 1997.

WARNING: A continued prosecution application "is a request to expressly abandon the prior application" as of its filing date. 37 C.F.R. § 1.53(d)(2)(v). Therefore, where the prior application is not to be abandoned, any continuation or divisional application must be filed under 37 C.F.R. § 1.53(b).

WARNING: While the filing of a continued prosecution application is the specific reference required by 35 U.S.C. § 120 to every application assigned the application number, identified in such request, no amendment in the application may delete the specific reference to any prior application (e.g., for patent term purposes). 37 C.F.R. § 1.53(d)(7).

WARNING: A request for an application under § 1.53(d) (CPA) cannot be submitted within papers filed for another purpose (e.g., the filing of a "conditional" request for a continued prosecution application within an amendment after final for the prior application). A "conditional" request for a CPA submitted (as a separate paper) with an amendment after final will be treated as an unconditional request for a CPA. This will result (§ 1.53(d)(2)(v)) in the abandonment of such prior application, and (if so instructed in the request for CPA) the amendment after final in the prior application will be treated as a preliminary amendment in the CPA. 62 FR 53131, 53140, October 10, 1997.

NOTE: "The filing date of a continued prosecution application is the date on which a request on a separate paper for an application . . . is filed." 37 C.F.R. § 1.53(d)(2)(emphasis added).

1. This is a request for the filing of a

- continuation
 divisional

continued prosecution application under 37 C.F.R. § 1.53(d) of the above-identified prior nonprovisional application.

WARNING: "A request for a CPA expressly abandons the prior application as of the filing date of the request for the CPA. See 37 C.F.R. § 1.53(d)(2)(v). Therefore, where the prior application is not to be abandoned, any continuation or divisional application must be filed under 37 C.F.R. § 1.53(b)." M.P.E.P. § 201.06(d), 7th ed.

It is further requested that this continued prosecution application utilize the file jacket and contents of the prior application, including the specification, drawings, and oath or declaration from the prior application, to constitute this new application, and that the application number of the above-identified prior application be assigned for identification purposes. 37 C.F.R. § 1.53(d)(2)(iv).

NOTE: Since a CPA cannot contain new matter, the oath or declaration filed in the prior nonprovisional application would supply all the information required under 35 U.S.C. § 111(a) and the rules to have a complete application and to obtain a filing date. Accordingly, the previously filed oath or declaration will be considered to be the oath or declaration of the CPA. M.P.E.P. § 201.06(d), 7th ed.

It is also requested that the above-identified prior application be expressly abandoned as of the filing date accorded this continued prosecution application. 37 C.F.R. § 1.53(d)(2)(v).

2. With respect to the above-identified prior nonprovisional application, this continued prosecution application is being filed:

- A. before the earliest of the:
- termination of the proceedings on the prior application (37 C.F.R. § 1.53(d)(1)(ii)(C))
 payment of the issue fee on the prior application (37 C.F.R. § 1.53(d)(1)(ii)(A)).
 abandonment of the prior application (37 C.F.R. § 1.53(d)(1)(ii)(B))

OR

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- B. after the payment of the issue fee — but a petition under § 1.313(b)(5) has been granted in the prior application. 37 C.F.R. § 1.53(d)(1)(ii)(A).

NOTE: *"If an extension of time is necessary to establish continuity between the prior application and the CPA, the petition for extension of time should be filed as a separate paper directed to the prior nonprovisional application. However, a CPA is not improper simply because the request for a CPA is combined in a single paper with a petition for extension of time. . . ."*

"While the filing of a CPA is not strictly a reply to an Office action mailed in a prior application, a request for a CPA is a paper directed to and placed in the file of the prior application, and seeks to take action in (i.e., expressly abandon) the prior application. Thus, it will be considered a 'reply' for purposes of 37 CFR 1.136(a)(3). As a result, an authorization in the prior application to charge all required fees, fees under 37 CFR 1.17, or all required extension of time fees to a deposit account will be treated as a constructive petition for an extension of time in the prior application for the purposes of establishing continuity with the CPA. The correct extension fee to be charged in the prior application would be the extension fee necessary to establish continuity between the prior application and the CPA on the filing date of the CPA."

"If an extension of time directed to the prior application is filed as a separate paper, it must be accompanied by its own certificate of mailing under 37 CFR 1.8 (if mailed by first class mail) or under 37 CFR 1.10 (if mailed by Express Mail), of the benefits of those rules are desired."

M.P.E.P. § 201.06(d), 7th ed.

- C. The term for response or taking action in the prior application expires on 9/24/99

An extension of time in the prior application is:

- filed concurrently in the prior application
 has been filed on _____

3. It is noted that:

- This application discloses and claims only subject matter disclosed in the prior application. 37 C.F.R. § 1.53(d)(2)(ii).
- Filing of this continued prosecution application is to be construed to include a waiver of confidentiality by the applicant under 35 U.S.C. § 122, to the extent that any member of the public, who is entitled under the provisions of § 1.14 to access to, copies of, or information concerning, either the prior application or any continuing application filed under the provisions of 37 C.F.R. § 1.53(d), may be given similar access to, copies of, or similar information concerning the other application or applications in the file jacket. 37 C.F.R. § 1.53(d)(6).
- Filing of this request is the specific reference required by 35 U.S.C. § 120 to every application assigned the application number identified in this request. No amendment in this application may delete this specific reference to any prior application. 37 C.F.R. §§ 1.53(d)(7) and 1.78(a)(2).

4. This continued prosecution application names as inventors:

- the same inventors named in the prior application on the date this continued prosecution application under 37 C.F.R. § 1.53(d)(2)(iii) is being filed.
- fewer than all the inventors named in the prior application. 37 C.F.R. § 1.53(d)(4).

NOTE: A CPA application may be filed by fewer than all the inventors named in the prior application, provided the request for an application under 37 C.F.R. § 1.53(d), when filed, is accompanied by a statement requesting deletion of the name(s) of the person(s) who are not the inventors of the invention being claimed in the new application. 37 C.F.R. § 1.53(d)(4).

- Please delete the following name(s) as inventor(s), who are not inventor(s) of the invention being claimed in this new application:
-
-

NOTE: "No person may be named as an inventor in an application filed under this paragraph who was not named as an inventor in the prior application on the date the application under this paragraph was filed, except by way of a petition under § 1.48." 37 C.F.R. § 1.53(d)(4).

NOTE: A request for an application under § 1.53(d) purporting to name as an inventor a person not named as an inventor in the prior application (even if accompanied by a new declaration/oath under § 1.63 listing that person as an inventor) will be treated as naming the same inventors named in the prior application (§ 1.53(d)(2)(iii)). 62 FR 53131, 53141, October 10, 1997.

- Please add the following name(s) as inventors:
-
-

- A petition under § 1.48 is attached.

5. Attached hereto is an amendment to the prior application as it existed prior to the filing of this continuation prosecution application.

NOTE: "Any new change must be made in the form of an amendment to the prior application as it existed prior to the filing of an application under this paragraph. No amendment in an application under this paragraph (a continued prosecution application) may introduce new matter or matter that would have been new matter in the prior application. Any new specification filed with the request for an application under this paragraph will not be considered part of the original application papers, but will be treated as a substitute specification in accordance with § 1.125. However, the applicant must comply with the requirements of 37 CFR § 1.125(b) before the substitute specification will be entered into the CPA." 37 C.F.R. § 1.53(d)(5).

WARNING: An amendment after final filing and refused entry in the prior application will not be automatically entered in the CPA and specific instructions to enter amendment(s) refused entry in the prior application must be filed. Q&A 64, "Changes in Patent Practice and Procedure," effective December 1, 1997, supplemented up to February 1, 1998.

WARNING: "The original disclosure of a CPA is the same as the original disclosure of the patent non-continued prosecution application and amendments entered in the parent application(s). However, any subject matter added by amendment in the parent application which is deemed to be new matter in the parent application will also be considered new matter in the CPA. No amendment filed in a CPA, even if filed on the filing date of the CPA, may include new matter." M.P.E.P § 201.06(d), 7th ed.

Please enter in this CPA application the unentered amendment under 37 C.F.R. § 1.116 filed in the prior application.

6. Information Disclosure Statement

NOTE: "All information disclosure statements filed in the prior application that comply with the content requirements of 37 CFR 1.98 will be considered in a CPA by the examiner. No specific request that the previously submitted information be considered in a CPA is required.

"In addition, all information disclosure statements that comply with the content requirements of 37 CFR 1.98 and are filed within three months of the filing date of a CPA will be considered by the examiner, regardless of whatever else has occurred in the examination process up to that point in time. Thus, in the rare instance that a final Office action or a notice of allowance is prepared and mailed prior to a date which is 3 months from the filing date of the CPA, any information contained in an information disclosure statement complying with 37 CFR 1.98, and filed within that 3-month window must be considered by the examiner. . . . [I]t should be expected that a first Office action will normally issue in a CPA well within three months from the filing date of the CPA request. The submission of an information disclosure statement after the first Office action is mailed could delay prosecution and result in the loss of patent term. Therefore, applicants are encouraged to file any information disclosure statement in a CPA as early possible, preferably before the first Office action. . . ." M.P.E.P § 201.06(d), 7th ed.

Enclosed is an Information Disclosure Statement in accordance with the requirements of 37 C.F.R. § 1.98.

7. Fee Calculation

NOTE: "(3) The filing fee for a continued prosecution application filed under this paragraph is:

(i) The basic filing fee as set forth in § 1.16; and

(ii) Any additional § 1.16 fee due based on the number of claims remaining in the application after entry of any amendment accompanying the request for an application under this paragraph and entry of any amendments under § 1.116 unentered in the prior application which applicant has requested to be entered in the continued prosecution application."

37 C.F.R. § 1.53(d)(3)(i) and (ii).

A. Regular application

CLAIMS AS FILED

Number filed	Number Extra	Rate	Basic Fee
			37 C.F.R. § 1.16(a) \$760.00
Total Claims 12 -20=	- 0 - X	\$18.00 =	- 0 -
(37 C.F.R. § 1.16(c))			
Independent Claims 1-3=	- 0 - X	\$78.00 =	- 0 -
(37 C.F.R. § 1.16(b))			
Multiple dependent claim(s), if any (37 C.F.R. § 1.16(d))	+	\$260.00	

- An amendment canceling extra claims is enclosed.
- An amendment deleting multiple-dependencies is enclosed.
- The fee for extra claims is not being paid at this time.

NOTE: If the fees for extra claims are not paid on filing, they must be paid or the claims canceled by amendment, prior to the expiration of the time period set for response by the Patent and Trademark Office in any notice of fee deficiency. 37 C.F.R. § 1.16(d).

Filing Fee Calculation \$ 760.00

B. Design application

(\$310.00—37 C.F.R. § 1.16(f))

Filing Fee Calculation \$ _____

C. Plant application

(\$480.00—37 C.F.R. § 1.16(g))

Filing Fee Calculation \$ _____

8. Small Entity Statement(s)

WARNING: *Small entity status must not be established unless the person(s) signing the statement can unequivocally make the required self-certification. M.P.E.P., § 509.03, 6th ed., rev. 2, July 1996. (emphasis added).*

- Statement(s) that this is a filing by a small entity under 37 C.F.R. §§ 1.9 and 1.27 is(are) attached.

WARNING: *"... Status as a small entity in one application or patent does not affect any other application or patent, including applications or patents which are directly or indirectly dependent upon the application or patent in which the status has been established. The refiling of an application under § 1.53 as a continuation, division, or continuation-in-part (including a continued prosecution application under § 1.53(d)), or the filing of a reissue application requires a new determination as to continued entitlement to small entity status for the continuing or reissue application. A nonprovisional application claiming benefit under 35 U.S.C. §§ 119(e), 120, 121 or 365(c) of a prior application, or a reissue application may rely on a statement filed in the prior application or in the patent if the nonprovisional application or the reissue application includes a reference to the statement in the prior application or in the patent or includes a copy of the statement in the prior application or in the patent if status as a small entity is still proper and desired. The payments of the small entity basic statutory filing fee will be treated as such a reference. . . ." 37 C.F.R. § 1.28(a)(2). (emphasis added).*

WARNING: *"Small entity status must not be established when the person or persons signing the . . . statement can unequivocally make the required self-certification." M.P.E.P., § 509.03, 7th ed. (emphasis added).*

(complete the following, if applicable)

- Status as a small entity was claimed in prior application

_____, filed on _____, from which benefit is being claimed for this application under:

- 35 U.S.C. § 119(e),
 120,
 121,
 365(c),

and which status as a small entity is still proper and desired.

- A copy of the statement in the prior application is included.

Filing Fee Calculation (50% of A, B, or C above) \$_____

NOTE: *Any excess of the full fee paid will be refunded if a small entity statement and a refund request are filed within 2 months of the date of timely payment of a full fee. The two-month period is not extendable under § 1.136. 37 C.F.R. § 1.28(a).*

9. Fee Payment Being Made at This Time

Not Enclosed

No filing fee is to be paid at this time.

NOTE: Since a general authorization to charge fees to a deposit account in the prior nonprovisional application carries over to the CPA, where the applicant desires to file the CPA without paying the filing fee on the filing date of the application, the applicant may file the CPA with specific instructions revoking the general authorization filed in the prior application. M.P.E.P § 201.06(d), 7th ed.

Applicant hereby revokes the general authorization to pay fees filed in the prior nonprovisional application of which this is a CPA.

(This and the surcharge required by 37 C.F.R. § 1.16(e) can be paid subsequently.)

Enclosed

NOTE: "An applicant filing a CPA by facsimile must include an authorization to charge the basic filing fee to a deposit account, or the application will be treated under 37 CFR 1.53(f) as having been filed without the basic filing fee (as fees cannot otherwise be transmitted by facsimile)." M.P.E.P § 201.06(d), 7th ed.

NOTE: A general authorization to charge fees to a deposit account filed in the prior nonprovisional application carries over to a CPA and, in such a situation, the necessary filing fee will be charged to the deposit account. M.P.E.P § 201.06(d), 7th ed.

Filing fee \$760.00

NOTE: Payment of a small entity basic filing fee will be treated as a reference to the statements in the prior application that status as a small entity is desired and proper. 37 C.F.R. § 1.28(a)(2).

<input type="checkbox"/> Recording assignment (\$40.00—37 C.F.R. § 1.21(h)) (See attached "COVER SHEET FOR ASSIGNMENT ACCOMPANYING NEW APPLICATION.")	<u>\$_____</u>
<input type="checkbox"/> Petition fee for filing by other than all the inventors or person on behalf of the inventor where inventor refused to sign or cannot be reached (\$130.00—37 C.F.R. §§ 1.47 and 1.17(l))	<u>\$_____</u>

Total fees enclosed **\$760.00**

10. Method of Payment of Fees

Check in the amount of **\$760.00**

Charge Account No. _____ in the amount of _____.
A duplicate of this transmittal is attached.

NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 C.F.R. § 1.22(b).

WARNING: Unless an application under § 1.53(d) filed by facsimile includes an authorization to charge the basic filing fee to a deposit account, the applicant will be given a notification requiring payment of the appropriate filing fee (§ 1.53(d)(3)) and the late filing surcharge under § 1.16(e) to avoid abandonment of the § 1.53(d) application. 62 Fed. Reg. 53,131, 53,133 (Oct. 10, 1997).

11. Authorization to Charge Additional Fees

WARNING: If no fees are to be paid on filing, the following items should not be completed.

WARNING: Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges, if extra claim charges are authorized.

- The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Account No. 13-4892
- 37 C.F.R. § 1.16(a), (f), or (g) (filing fees)
- 37 C.F.R. § 1.16(b), (c), and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid on these claims canceled by amendment prior to the expiration of the time period set for response by the P.T.O. in any notice of fee deficiency (37 C.F.R. § 1.16(d)), it might be best not to authorize the P.T.O. to charge additional claim fees, except possibly when dealing with amendments after final action.

- 37 C.F.R. § 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)
- 37 C.F.R. § 1.17(a)(1)-(5) (extension fees pursuant to § 1.136(a))
- 37 C.F.R. § 1.17 (application processing fees)

WARNING: "A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. § 1.136(a)(3).

- 37 C.F.R. § 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. § 1.311(b))

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the Notice of Allowance. 37 C.F.R. § 1.311(b).

NOTE: 37 C.F.R. § 1.28(b) requires "Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying, . . . issue fee." From the wording of 37 C.F.R. § 1.28(b), (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

12. Instructions as to Overpayment

NOTE: "Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).

- Credit Account No. 13-4892
- Refund

Date: 10/28/99
Reg. No. 20,532
Tel. No. (626) 584-0396

Customer No.



SIGNATURE OF PRACTITIONER

Joseph E. Mueth, Esq.

(*type or print name of practitioner*)

225 South Lake Avenue, 8th Floor

P.O. (Correspondence) Address
Pasadena, CA 91101



107-145D-C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:) Group Art Unit: 1641
SAID EL SHAMI)
Serial No.: 09/036,819) Examining Attorney:
Filed: March 9, 1998) S. Devi, Ph.D.
For: METHOD FOR MEASURING FREE) Date: September 17, 1999
LIGANDS IN BIOLOGICAL) Pasadena, California
FLUIDS, AND ASSAY KITS)
FOR MEASURING SAME)

AMENDMENT UNDER RULE 116

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Sir:

Responsive to the Office Action of June 24, 1999.

In the claims, please cancel claim 41 and re-write that claim as follows:

53. A method for measuring the concentration of free testosterone ligand in a biological fluid in the presence of bound ligand and endogenous binding proteins, without disturbing the equilibrium between said free ligand and protein-bound ligand, which method comprises

(a) incubating, a sample of the biological fluid with (i) a

ligand analog tracer which, due to its chemical structure, does not bind to some of the endogenous binding proteins, (ii) a concentration of a specific ligand binder and (iii) a concentration of a specific inhibitor agent that inhibits the binding of the ligand analog tracer to at least one other endogenous binding protein;

- (b) separating the ligand analog tracer bound to the specific ligand binder from unbound tracer; and
- (c) determining the concentration of said free ligand in said biological fluid.

Please amend further as follows:

Claim 42, line 1, change "41" to "53".

Claim 43, line 1, change "41" to "53".

Claim 44, line 1, change "41" to "53".

Claim 45, line 1, change "41" to "53".

Claim 46, line 1, change "41" to "53".

Claim 47, line 1, change "41" to "53".

Claim 48, line 1, change "41" to "53".

Claim 50, line 1, change "41" to "53".

Claim 51, line 1, change "41" to "53".

Claim 52, line 1, change "41" to "53".

Please cancel all of the drawings.